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RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

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Attorneys for Defendants
ETHICON, INC. (on its own behalf and behalf of its Division, ETHICON WOMEN'S HEALTH & UROLOGY, and erroneously sued as GYNECARE, INC.); and JOHNSON & JOHNSON

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

JCS

DIANE McIRVIN, an individual; and ALICE GALE WILSON, an individual,

Plaintiffs,

v.

GYNECARE, INC., a California corporation; ETHICON, INC., a New Jersey corporation; JOHNSON & JOHNSON, a New Jersey corporation; and DOE MANUFACTURES ONE through ONE HUNDRED,

Defendants.

Case No. CV11 0697

DECLARATION OF MICHELLE A. CHILDERS IN SUPPORT OF NOTICE OF REMOVAL AND REMOVAL OF ACTION UNDER 28 U.S.C. § 1441(B) (DIVERSITY) OF DEFENDANTS ETHICON, INC. (on its own behalf and behalf of its Division, ETHICON WOMEN'S HEALTH & UROLOGY, and erroneously sued as GYNECARE, INC.); and JOHNSON & JOHNSON

I, MICHELLE A. CHILDERS, declare:

1. I am an attorney admitted to practice before all courts of the State of California and am a Partner with Drinker Biddle & Reath, LLP, attorneys for ETHICON, INC. (on its own behalf and behalf of its Division, ETHICON WOMEN'S HEALTH & UROLOGY, and erroneously sued as GYNECARE, INC.) ("Ethicon"); and JOHNSON & JOHNSON ("J&J") (collectively "Defendants") in this action. I make this Declaration based on my personal knowledge in support of Defendants' Removal of *Diane McIrvin and Alice Gale Wilson v.*

Gynecare, Inc. et al., filed in the Superior Court of the State of California, County of San Francisco, Case No. CGC-10-506696, to this Court. I would and could competently testify to the matters stated in this Declaration if called as a witness.

2. Attached hereto as **Exhibit A** is a true and correct copy of the Complaint in this action.

3. The earliest service on Defendants in this action was made on J&J on January 17, 2011.

4. Attached hereto as **Exhibit B** is a true and correct copy of the respective Answers of Defendants to the Complaint in this action, filed by Defendants on February 14, 2011.

5. The Complaint and Defendants' Answers are the only state court pleadings known to Defendants to have been filed in this action.

6. I have reviewed reports of verdicts and settlements in cases in California brought by plaintiffs alleging injuries similar to those alleged in this case, including those alleging severe pain, corrective surgeries, and dyspareunia, *inter alia*. For example, in *Casadei v. Norris*, Los Angeles Cty. Super. Ct., Case No. BC161172, plaintiffs claimed injuries including severe pain, dyspareunia, three corrective surgeries, and loss of consortium. They were awarded damages in the amount of $530,415.00. *See* 31 Trials Digest 3d 113, a true and correct copy of which is attached hereto as **Exhibit C**. In *Penix v. Martin*, Los Angeles Cty. Super. Ct., Case No. LC038378, plaintiff alleged vaginal scarring and permanent dyspareunia, *inter alia*. Plaintiff was awarded a verdict in the amount of $116,661.00. *See* 12 Trials Digest 3d 45, a true and correct copy of which is attached hereto as **Exhibit D**. Given the similarity between the injuries alleged in those and other cases I reviewed and the injuries alleged by Plaintiffs here, and based on over a decade experience defending products liability actions, it is facially evident from the Complaint that Plaintiffs have placed in excess of $75,000.00 in controversy, exclusive of interest and costs.

7. Defendants will file a Notice Of Filing Notice Of Removal And Removal Of Action with the Clerk of the San Francisco County Superior Court and will serve Plaintiffs' counsel with a copy.

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I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 16 day of February, 2011 in San Francisco, California.

Michelle A. Childers

EXHIBIT A

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BY: _____ DEPUTY CLERK
D. STEPPE

SUPERIOR COURT OF CALIFORNIA
COUNTY OF SAN FRANCISCO – CIVIC CENTER

CGC-10-506696

DIANE MC IRVIN, an individual, and ALICE GALE WILSON an individual

Plaintiffs,

vs.

GYNECARE, INC. a California Corporation; ETHICON, INC. a New Jersey corporation, JOHNSON & JOHNSON, a New Jersey corporation, DOE MANUFACTURERS one through one hundred.

Defendants.

CASE NO.

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

1. Strict Products Liability- Failure to Warn
2. Strict Liability
3. Negligence
4. Breach of Implied Warranty
5. Breach of Express Warranty
6. Fraud
7. Fraud by Concealment
8. Negligent Misrepresentation
9. Violation of State Consumer Fraud & Deceptive Trade Practices Act

COME NOW, plaintiffs complaining of defendants as follows:

PARTIES, JURISDICTION AND VENUE

1. DIANE MC IRVIN, is and was at all times alleged herein, a citizen and resident of Chula Vista, California. ALICE GALE WILSON, is and was at all times alleged herein, a citizen and resident of Burnettsville, Indiana.

2. Defendant GYNECARE, INC. (hereinafter, "GYNECARE") is and was a corporation formed under the laws of the State of California, with its principal place of business at 235 Constitution Drive, Menlo Park, California 94025.

3. At all times alleged herein, GYNECARE included and includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

4. In or around October 1997, GYNECARE merged with ETHICON, INC.

5. At all times alleged herein, GYNECARE conducted regular and sustained business in California by selling and distributing its products in California, as described below.

6. Defendant ETHICON, INC. (hereinafter, "ETHICON"), at all times alleged herein, is and was a corporation formed under the laws of the State of New Jersey, with its principal place of business at US Route 22 West, Sommerville, New Jersey 08876.

7. At all times alleged herein, ETHICON includes and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

8. At all times alleged herein, ETHICON conducted regular and sustained business in California , by selling and distributing its products in California, as described below. By these same activities, ETHICON has sufficient contacts witin the State of California to subject it to the jurisdiction of this court.

9. Defendant JOHNSON & JOHNSON, INC. (hereinafter, "J&J"). at all times alleged herein, is and was a corporation formed under the laws of the State of New Jersey, with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

10. At all times alleged herein, J&J includes and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors,

successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

11. At all times alleged herein, J&J conducted regular and sustained business in California by selling and distributing its products in California, as described below. By these same activities, J&J has sufficient contacts with the State of California, to subject it to the jurisdiction of this Court.

12. Upon information and belief, ETHICON is a wholly owned subsidiary of J&J.

13. Upon information and belief, Defendants DOE Manufacturers One through One Hundred are manufacturers, persons, agents, servants, employees, corporations, partnership or other business entities whose true names are unknown by Plaintiff at the present time. Plaintiffs allege, upon information and belief, that DOE Manufacturers ONE through One Hundred are citizens and residents of the State of California, or are domiciled within the State of California, or conduct regular and sustained business within the State of California, to subject them to the jurisdiction of this Court. Each of these Defendants negligently assisted the named Defendants in carrying out the allegations as set forth below. Alternatively, DOE Manufacturers One through One Hundred were agents and/or servants of one or more named defendants, were acting within the course and scope of their employment and/or agency at the times alleged herein. If and when the true identities of such persons, servants, employees, corporations, partnership or other business entities are known to Plaintiff, they will seek leave of Court to amend the Complaint to reflect such true names, together with appropriate charging allegations.

14. At all times alleged herein, reference to any named Defendant, or use of the collective term "Defendants", includes the named Defendant and Defendants DOE Manufacturers ONE through one hundred, or all named Defendants herein and Defendants DOE Manufacturers ONE through one hundred, respectively.

15. At all times alleged herein, Defendants identified herein as, or discovered to be, corporations or other business entities were acting by and through officers, employees, agents, and contractors, who were acting within the course and scope of said office, employment, agency, or contractual authority.

FACTUAL BACKGROUND

16. Defendants design, research, develop, manufacture, test, market, advertise, promote, distribute, and sell products that are sold to and marketed to treat, among other things, pelvic organ prolapse and stress urinary incontinence.

17. GYNECARE, ETHICON, and J&J designed, researched, developed, manufactured, tested, marketed, advertised, promoted, distributed, and sold mesh products, the implanted synthetic surgical mesh devices purported to correct and restore normal vaginal structure secondary to pelvic organ prolapse.

18. The ETHICON mesh products are collectively referred to herein as the "Mesh Devices."

19. Upon information and belief, ETHICON sought and obtained Food and Drug Administration ("FDA") approval to market mess products and/or its monofilament polypropylene mesh component under Section 510(k) of the Medical Device Amendment.

20. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices without formal review for safety or efficacy.

21. On or about November, 2010, Plaintiff DIANE MCIRVIN underwent transvaginal tape, bladder sling, urethral suspension, and revision of mesh erosion repair. On or about December 30, 2008, Plaintiff ALICE GALE WILSON underwent transvaginal tape, bladder sling, urethral suspension, and revision of mesh erosion repair. Since implantation of the Mesh Devices, Plaintiffs have suffered from, among other problems, erosion, shrinkage, and extrusion of mesh from one or more of the Mesh Devices, causing urinary retention, severe persistent pain, including dyspareunia, and numerous surgical procedures to remove the Mesh Devices.

22. As early as 2004 until the present, Defendants have received numerous reports of adverse events filed by physicians and patients pertaining to their synthetic mesh systems, and were aware or should have been aware of many similar reports concerning substantially equivalent products by other manufacturers. The most frequent complaints were erosion, extrusion, inflection, hardening of the mesh, chronic pain, and worsening dyspareunia. Studies show the rate of mesh erosion was 13 percent accompanied by worsening dyspareunis rates as high as 63 percent. Analysis of the first 100 vaginal mesh procedures revealed a 17.5 percent erosion rate.

23. The 2004 World Health Organization 3rd International Consultation on Incontinence reported mesh repairs have an unacceptably high rate of complication that includes erosion, extrusion, infection, sepsis, and

dyspareunia. Because of the poor risk/benefit ratio of the vaginal mesh systems it was recommended the synthetic mesh systems not to be used until more approved clinical trials of outcome were conducted.

24. At all times relevant herein, the Mesh Devices were widely advertised and promoted by Defendants as a safe and effective treatment for pelvic organ prolapse, rectocele, enterocele and stress urinary incontinence. Said Defendants, and each of them, minimized the risks posed to patients with implantation of the Mesh Devices.

25. At all times relevant herein, Defendants knew their Mesh Devices were defective and knew the defect was attributable to the erosion, hardening and shrinkage of the mesh material. The Defendants, and each of them, knew that the Mesh Devices were made to allow tissue infiltration and that removal is not advised. Complications from the mesh and from mesh removal are life-changing and can be irreversible. This information was known to the Defendants, and each of them, prior to implantation of the Mesh Devices in Plaintiffs.

26. At all times relevant to this action, the Defendants, and each of them, knew that synthetic mesh systems, and specifically the Mesh Devices, were not safe for the patients for whom they were prescribed and implanted, because the mesh eroded and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing injuries from erosion, extrusion, infection, sepsis, chronic foreign body invasion, dense adhesions, and worsening dyspareunia. Removal of eroded or infected mesh brings a high rate of life-threatening complications including permanent disfigurement and hemorrhage. Complete removal can take multiple surgical interventions in the operating theater and results in scarring on fragile compromised pelvic tissue and muscles.

27. The Defendants' representations regarding the performance of the Mesh Devices, including, but not limited to, the consistency of the performance of the Mesh Devices and their safety and reliability, were untrue as set forth in the published literature and adverse event reports. The Defendants, and each of them, failed to disclose to physicians, patients or Plaintiff that their Mesh Devices were subject to erosion or scar tissue formation causing the injuries herein described.

28. At all relevant times herein, Defendants, and each of them, continued to promote the Mesh Devices as safe and effective even when no clinical trials had been done supporting long or short term efficacy.

29. In doing so the Defendants, and each of them, concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Mesh Devices for pelvic organ prolapse, rectocele, enterocele and stress urinary incontinence.

30. As a result of the defective Mesh Devices, Plaintiffs have suffered severe physical and emotional injuries, including and but limited to, multiple surgical procedures, painful scarring and worsening and continuing dyspareunia.

31. At all relevant times herein, Defendants, and each of them, failed to provide sufficient warnings and instructions that would have put Plaintiffs and the general public on notice of the dangers and adverse effects caused by implantation of the Mesh Devices including, but not limited to, mesh erosion, dense adhesion, worsening dyspareunia, chronic pain, inflection, sepsis, permanent disfigurement and multiple surgeries for mesh removal.

32. The Mesh Devices are designed, manufactured, distributed sold and/or supplied by the Defendants, and each of them, was defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants'' knowledge of product failure and serious adverse events.

33. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in , authorized and/or directed the production and promotion of the aforementioned products when they knew of the hazards and dangerous propensities of said products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff.

34. Due to the acts of all Defendants individually or in concert, the information regarding the nature and/or the facts leading up to and/or causing the injuries alleged herein was not known by Plaintiffs nor reasonably could have been known prior to October 20, 2008, when the FDA released a public health notification of the serious complications associated with transvaginal placement of surgical mesh devices, like the Mesh Devices at issue here, for treatment of, *inter alia*, pelvic organ prolapse, rectocele, enterocele, and stress urinary incontinence.

FIRST CAUSE OF ACTION

[Strict Products Liability – Failure to Warn]

35. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs.

36. At all times mentioned herein, the Mesh Devices are, and were, dangerous and presented a substantial danger to patients who were implanted with the Mesh Devices, and these risks and dangers were known or knowable at the time of distribution and implantation in PlaintiffS. Ordinary consumer would not have recognized the potential risks and dangers the Mesh Devices posed to pelvic reconstruction patients because their uses were specifically promoted to improve the health of such patients. The Mesh Devices were used in a way reasonably foreseeable to the Defendants, and each of them, by Plaintiffs. The Defendants, and each of them, failed to provide warning of such risks and dangers to Plaintiffs and their medical providers as described herein.

37. At all times mentioned herein, the Mesh Devices are, and were, dangerous and presented a substantial danger to patients who were implanted with the Mesh Devices, and these risks and dangers were known or knowable at the time of distribution and implantation in Plaintiffs. Ordinary consumers would not have recognized the potential risks and dangers the Mesh Devices posed to pelvic reconstruction patients because their uses were specifically promoted to improve the health of such patients. The Mesh Devices were used in a way reasonably foreseeable to the Defendants, and each of them, by Plaintiffs. The Defendants, and each of the, failed to provide warning of such risks and dangers to Plaintiffs and their medical providers as described herein.

38. As a result of the Mesh Devices, Plaintiffs suffered debilitating injuries from the synthetic mesh including mesh erosion, shrinking, hardening, chronic pain and worsening dyspareunia leading to the need for dangerous and serious vaginal surgery; required and will continue to require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, chronic debilitating pain, and other such damages.

39. In doing the acts herein described, the Defendants, and each of them, acted with oppression, fraud and malice, and Plaintiffs are therefore entitled to punitive damages to deter the Defendants, and each of them, and others from engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of the Defendants.

WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

SECOND CAUSE OF ACTION

[Strict Liability]

40. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation continued in the preceding paragraphs.

41. The Mesh Devices were manufactured and/or supplied by the Defendants, and each of them, and were placed into the stream of commerce by these Defendants, and each of them, in a defective and unreasonably dangerous condition in that the foreseeable risks exceeded the benefits associated with their design of formulation.

42. Alternatively, the Mesh Devices manufactured and/or supplied by the Defendants, and each of them, were defective in design or formulation, inadequate warning or instruction and/or inadequate post-marketing warnings or instructions in that when they were placed into the stream of commerce, they were unreasonably dangerous; they were more dangerous than an ordinary consumer would expect and more dangerous than other forms of pelvic organ prolapse, rectocele, enterocele and stress urinary incontinence repair/correction. As a result of the defective unreasonably dangerous condition of the Mesh Devices manufactured and/or supplied by the Defendants, and each of them, Plaintiffs were caused to suffer the herein described injuries and damages.

43. Defendants, and each of them, acted with conscious and deliberate disregard of the foreseeable harm caused by the Mesh Devices.

44. The Defendants, and each of them, thereby acted with fraud, malice, oppression and a conscious disregard for the Plaintiffs' and the general public's safety, who accordingly request that the trier of fact, in the exercise of sound discretion, award additional damages for the sake of example and for the purpose of punishing the Defendants, and each of them, for their conduct, in am amount sufficiently large to be an example to others and to deter the Defendants, and each of them, and others from engaging gin similar conduct in the future. The aforesaid wrongful conduct was done with the advance knowledge, authorization, and/or ratification of an officer, director, and/or managing agents of the Defendants.

WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

THIRD CAUSE OF ACTION

[Negligence]

45. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs.

46. The Defendants, and each of them, and their representatives were manufacturers and/or distributors of the Mesh Devices. At all times herein, the Defendants, and each of them, had a duty to properly manufacture, compotmd, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings and prepare for use and sell the aforesaid products.

47. The Defendants, and each of them, so negligently and carelessly manufactured, compounded, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the aforesaid products, that there were dangerous and unsafe for the use and purpose for which they were intended, that is, repairing/correcting pelvic organ prolapse, rectocele, enterocele and stress urinary incontinence, in Plaintiffs and others similarly situated. As a result of the carelessness and negligence of the Defendants, Plaintiffs have the Mesh Devices implanted in the manner intended by the manufacturer, and, as a result, Plaitniffs suffered the injuries and damages described herein.

WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

FOURTH CAUSE OF ACTION

[Breach of Implied Warranty]

48. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs.

49. The Defendants, and each of them, impliedly warranted that their Mesh Devices, which the Defendants, and each of them, designed, manufactured, assembled, promoted and sold to Plaintiffs, were merchantable and fit and safe for ordinary use. The Defendants, and each of them, further impliedly

warranted that their Mesh Devices were fit for the particular purpose of repairing/correcting pelvic organ prolapse, rectocele, enterocele and stress urinary incontinence, respectively.

50. The Defendants' Mesh Devices were defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiffs to severe and permanent injuries. Therefore, the Defendants, and each of them, breached the implied warranties of merchantability and fitness for a particular purpose when their synthetic mesh systems were sold to Plaintiffs, in that the Mesh Devices are defective and have failed to function as represented and intended.

51. As a result of the Defendants', and each of them, breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiffs have sustained and will continue to sustain the injuries and damages described herein and is, therefore, entitled to compensatory damages.

52. After Plaintiffs were made aware that their injuries were as a result of the Mesh Devices, said Defendants, and each of them, had ample and sufficient notice of the breach of said warranty.

WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

FIFTH CAUSE OF ACTON

[Breach of Express Warranty]

53. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs.

54. The Defendants and each of them, expressly warranted to Plaintiff and/or her authorized agents or sales representatives, in publications, and other communications intended for medical patients, and the general public, that the Mesh Devices were safe, effective, fit and proper for their intended use.

55. Plaintiffs and their physicians reasonably relied upon the skill and judgment of the Defendants, and upon said express warranty, in using the aforesaid Mesh Devices. The warranty and representations were untrue in that the products caused severe injury to Plaintiffs and were unsafe and, therefore, unsuited for the use in which they were intended and caused Plaintiffs to sustain damages and injuries herein alleged.

56. As soon as the true names of the Mesh Devices, and the fact that the warranty and representations were false, were ascertained, said Defendants, and each of the, had ample and sufficient notice of the breach of said warranty.

WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

SIXTH CAUSE OF ACTION

[FRAUD]

57. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs.

58. The Defendants, and each of them, falsely and fraudulently represented to Plaintiffs, their physicians, and to members of the general public tha the aforesaid products were safe, effective, reliable, consistent, and beter than the other similar pelvic repair procedures when used in the manner intended by the manufacturer. The representations by said Defendants, and each of them, were in fact, false. The true facts include, but are not limited to, that the aforesaid products were not safe to be used for repairing/correcting pelvic organ prolapse, rectocele, enterocele and stress urinary incontinence, and were, in fact, dangerous to the health and body of Plaintiffs.

59. When the Defendants, and each of them, made these representations, they were that they were false. The Defendants, and each of them, made said representations with the intent to defraud and deceive Plaintiffs, and with the intent to induce Plaintiffs to act in the manner herein alleged, that is to use the aforementioned products for repairing/correcting pelvic organ prolapse, rectocele, enterocele and stress urinary incontinence.

60. In doing the acts herein alleged, the Defendants, and each of them, acted with oppression, fraud, and malice, and Plaintiffs are, therefore, entitled to punitive damages to deter the Defendants, and each of them, and others form engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director, and/or managing agent of Defendants.

WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

SEVENTH CAUSE OF ACTION

[Fraud by Concealment]

61. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs.

62. At all times mentioned herein, the Defendants, and each of them, had the duty and obligation to disclose to Plaintiffs and to her physicians, the true facts concerning the Mesh Devices; that is, that said products were dangerous and defective, lacking efficacy for their purported use and lacking safety in normal use, and how likely there were to cause serious consequences to users including permanent and debilitating injuries. The Defendants, and each of them, made the affirmative representations as set forth above to Plaintiffs, their physicians, and the general public prior to the date the Mesh Devices were implanted in Plaintiffs, while concealing material facts.

63. At all times herein mentioned, the Defendants, and each of them, willfully, and maliciously concealed facts as set forth above from Plaintiffs and their physicians with the intent to defraud.

64. At all times herein mentioned, neither Plaintiffs nor their physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representation of safety and efficacy and utilized the Mesh Devices for repairing/correcting pelvic organ prolapse, rectocele, enterocele, and stress urinary incontinence.

65. As a result of the concealment of the facts set forth above, Plaintiffs sustained injuries as hereinafter set forth.

WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

EIGHTH CAUSE OF ACTION

[Negligent Misrepresentation]

66. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in the pending paragraphs.

67. At all relevant times herein, the Defendants, and each of them, represented to Plaintiffs and their physicians that the Mesh Devices were safe to use for repairing/correcting pelvic organ prolapse, rectocele, enterocele and stress urinary incontinence, knowing that the Mesh Devices were defective and capable of causing the injuries described herein.

68. The Defendants, and each of them, made the aforesaid representations with no reasonable ground for believing them to be true when the data readily available to Defendants, and upon information and belief directly available to Defendants in the form of adverse even reports specifically related to the Mesh Devices showed the Mesh Devices to be defective and dangerous when used in the intended manner.

69. The aforesaid representation were made to the physicians prescribing the Mesh Devices prior to the date they were prescribed to Plaintiffs with the intent that Plaintiffs and their physicians rely upon such misrepresentations about the safety and efficacy of the Mesh Devices. Plaintiffs and their physicians did reasonably rely upon such representations that the aforesaid product was safe for use for repairing/correcting pelvic organ prolapse, rectocele, enterocele and stree urinary incontinence.

70. The representations by the Defendants, and each of them, to Plaintiffs were false and thereby caused Plaintiffs' injuries described herein.

WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

NINTH CAUSE OF ACTION

[Violation of State Consumer Fraud & Deceptive Trade Practices Act]

71. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation contained in the pending paragraphs.

72. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of the Mesh Devices to Plaintiffs.

73. Defendants engaged in unfair, unconscionable, deceptive, fraudulent, and misleading act or practices in violation of all California and Colorado consumer protection laws, identified below. Through its false, untrue and misleading promotions of the Mesh Devices and/or local anesthetic products, Defendants induced Plaintiffs to purchase and/or pay for the purchase of the Mesh Devices. Defendants misrepresented the alleged benefits and characteristics of said products; suppressed, concealed, and failed to disclose material information concerning known adverse effects; misrepresented the quality as compared to much lower-cost alternatives; misrepresented and advertised that they were of a particular standard quality or grad that they were not; misrepresented in such a matter that later, on disclosure of the true facts, there was a likelihood that Plaintiffs would have switched to another product and/or chosen not to purchase and/or reimburse for purchase for the product; advertised with the intent not to sell as advertised; and otherwise engaged in fraudulent and deceptive conduct.

74. As such a matter that later, on disclosure of the true facts, there was a likelihood that Plaintiffs would have switched to another product and/or chosen not to purchase and/or reimburse for purchase for the

product; advertised with the intent not to sell as advertised; and otherwise engaged in fraudulent and deceptive conduct.

75. Moreover, Defendants knowingly took advantage of Plaintiffs who were reasonably unable to protect their interest due to ignorance of the harmful adverse effects. Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable and substantially injurious to Plaintiffs and offends the public conscience.

76. As a result of and in reliance of Defendants' violative conduct, Plaintiffs purchased and/or paid for purchases of the Mesh Devices that were not made for resale.

77. As such, Defendants engaged in unfair competition or deceptive acts or practices in violation of California Business & Professional Code §17200, *et seq.*, California Business & Professional Code §17500, *et seq.*, and C.R.S. 6-1-105, *et seq.*, among a proximate result of Defendants' misrepresentations and omissions, Plaintiffs have suffered ascertainable losses, in an amount to be determined at trial.

78. As a direct and proximate consequence of Defendants' acts, omissions and misrepresentations described herein, the Plaintiffs have required and will require healthcare and services; have incurred and will continue to incur medical and related expenses; have suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, and other such damages. Plaintiffs' direct medical losses and costs include care of hospitalization, physician car, monitoring, treatment, medications, and supplies. Plaintiffs will continue to incur such losses in the future.

79. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth, seeking compensatory damages, the imposition of a constructive trust over and restitution of the monies collected and profits realized by the Defendants to cease such false and misleading advertising in the future, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

a. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiffs, health care costs, medical monitoring, together with interest and costs as provided by law;

b. For lost wages and loss of earning capacity in an amount to be proven at time of trial together with interest thereon at the highest lawful rate from the date of judgment until paid in full;

c. For imposition of a constructive trust and restitution;

d. For punitive or exemplary and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

e. For any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue in which this case will be transferred for trial'

f. For Plaintiffs' reasonable attorneys' fees;

g. For Plaintiffs' costs incurred herein together with interest thereon at the highest lawful rate from the date of judgment until paid in full; and

h. For such other relief as the Court deems just and proper.

Dated: December 16, 2010

Girardi & Keese

By: _____

Thomas V. Girardi
Amy Fisch Solomon
Amanda Kent

Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues so triable.

Dated: December 16, 2010

Girardi & Keese

By: _____

Thomas V. Girardi
Amy Fisch Solomon
Amanda Kent

Attorneys for Plaintiff

EXHIBIT B

MICHELLE A. CHILDERS (SBN #197064)
NATHAN D. CARDOZO (SBN #259097)
DRINKER BIDDLE & REATH LLP
50 Fremont Street, 20th Floor
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Attorneys for Defendants
ETHICON, INC. (on its own behalf and behalf of its Division, ETHICON WOMEN'S HEALTH & UROLOGY, and erroneously sued as GYNECARE, INC.); and JOHNSON & JOHNSON

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DIANE McIRVIN, an individual; and ALICE GALE WILSON, an individual,

Plaintiffs,

v.

GYNECARE, INC., a California corporation; ETHICON, INC., a New Jersey corporation; JOHNSON & JOHNSON, a New Jersey corporation; and DOE MANUFACTURERS ONE through ONE HUNDRED,

Defendants.

Case No. CGC-10-506696

ANSWER OF ETHICON, INC. TO COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

GENERAL DENIAL

Defendant ETHICON, INC. (on its own behalf and behalf of its Division, ETHICON WOMEN'S HEALTH & UROLOGY, and erroneously sued as GYNECARE, INC.) ("Ethicon")[1] by and through its attorneys of record Drinker Biddle & Reath LLP, hereby answers the unverified Complaint for Damages and Demand for Jury Trial ("Complaint") as follows:

[1] Plaintiffs have erroneously sued GYNECARE, INC., a California corporation. Gynecare Inc., a Delaware corporation, was acquired by Ethicon, Inc. on November 19, 1997. Gynecare merged out of existence and into Ethicon, Inc. on January 3, 2000.

By virtue of the provisions of Cal. Civ. Proc. Code § 431.30, Ethicon generally denies each and every allegation in the Complaint that relates to or is directed to Ethicon or any of its alleged agents, servants or employees. Ethicon further denies that Plaintiffs have been damaged to any extent or amount or are entitled to any relief whatsoever from Ethicon.

Ethicon additionally denies that there is any law, fact, theory or contractual or legal relationship under which Plaintiffs are entitled to damages in any amount by this answering Defendant.

DEFENSES

FIRST DEFENSE

The Complaint fails to allege facts relating to Plaintiffs' fraud claim and Plaintiffs' claims under the consumer protection acts of Plaintiffs' states of residence with the particularity required by applicable law and is therefore insufficient to state a cause of action for fraud upon which relief can be granted.

SECOND DEFENSE

Some or all of Plaintiffs' claims may be barred by the applicable statutes of limitations and/or statutes of repose in the States of California, Colorado or Indiana.

THIRD DEFENSE

Plaintiffs may be barred from bringing some of the claims alleged in the Complaint because Plaintiffs may lack standing and/or capacity to bring such claims.

FOURTH DEFENSE

Plaintiffs may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

FIFTH DEFENSE

The United States District Court for the Northern District of California (San Francisco Division) has jurisdiction of this case under 28 U.S.C. §§ 1332 and 1441. Diversity of citizenship exists between Plaintiff and Defendants, and it is facially evident from the Complaint that the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

SIXTH DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the product at issue in this case and thus the "last clear chance" and assumption of the risk doctrines bar in whole or in part the damages Plaintiffs seek to recover herein.

SEVENTH DEFENSE

At all times mentioned herein, Plaintiffs were negligent, careless and at fault and conducted themselves so as to contribute substantially to their alleged injuries, losses, and damages. Said negligence, carelessness and fault of Plaintiffs bars in whole or in part the damages which Plaintiffs seek to recover herein.

EIGHTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were caused by the acts or omissions of third parties for which Ethicon has no legal responsibility.

NINTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use which was made of said product.

TENTH DEFENSE

Ethicon states that the sole proximate cause of the injuries and/or damages alleged by Plaintiffs was the actions, omissions, or negligence of a person or persons, other than Ethicon, for whose actions, omissions, or negligence Ethicon is in no way liable. Plaintiffs are not, therefore, entitled to recover from Ethicon in this action. As to Plaintiffs or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of Plaintiffs, if any, Ethicon expressly pleads the doctrines of contributory negligence and/or comparative fault and the provisions of any applicable comparative fault or contributory negligence statute, law or policy of the States of California, New Jersey, Colorado, or Indiana.

ELEVENTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at

issue in this case, if any, were not legally caused by the product at issue, but instead were legally caused by intervening and superseding causes or circumstances.

TWELFTH DEFENSE

Plaintiffs' claims and the defenses thereto are governed by the laws of a foreign jurisdiction.

THIRTEENTH DEFENSE

At all relevant times, Ethicon was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360c et seq., to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and other federal statutes and regulations, and Plaintiffs' claims are accordingly barred.

FOURTEENTH DEFENSE

The products at issue were accompanied by an adequate warning.

FIFTEENTH DEFENSE

Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the United States Food and Drug Administration ("FDA") is charged under law with determining the content of warnings and labeling for medical devices.

SIXTEENTH DEFENSE

Plaintiffs cannot state a claim with regard to warnings and labeling for medical devices because the remedy sought by Plaintiffs is subject to the exclusive regulation of the FDA.

SEVENTEENTH DEFENSE

Plaintiffs' alleged damages, if any, are barred in whole or in part by Plaintiffs' failure to mitigate such damages.

EIGHTEENTH DEFENSE

Plaintiffs' claims for pain and suffering are barred because they violate Ethicon's rights to procedural and substantive due process and equal protection as guaranteed by the Constitutions of the United States and the States of California, New Jersey, Colorado and Indiana.

NINETEENTH DEFENSE

The liability of Ethicon, if any, for Plaintiffs' non-economic loss must be apportioned in accordance with the provisions of CAL. CIV. CODE § 1431.2 or any similar law of the States of New Jersey, Colorado or Indiana.

TWENTIETH DEFENSE

The injuries resulting from the use of the product(s) referred to in the Complaint, if any, were not foreseeable to Ethicon given the state of scientific knowledge and state-of-the-art at the time of the alleged injuries. At all times relevant, the product(s) conformed to state-of-the-art specifications and state-of-scientific knowledge for such product at that time, as well as all applicable statutes and regulations, including those of the FDA.

TWENTY-FIRST DEFENSE

In the event Ethicon is held liable to Plaintiffs, which liability is expressly denied, and any other co-Defendants are also held liable, Ethicon is entitled to a percentage contribution of the total liability from said co-Defendants in accordance with principles of equitable indemnity and comparative contribution and pursuant to any applicable contribution or apportionment statute, law or policy of the States of California, New Jersey, Colorado or Indiana.

TWENTY-SECOND DEFENSE

Plaintiffs' claims against Ethicon are barred by the doctrines of equitable estoppel, laches, consent, waiver, res judicata, and collateral estoppel. Additionally, if either Plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Complaint or files for bankruptcy at some point in the future, the claims of any such Plaintiff may be "property of the bankruptcy estate" which should be prosecuted by the bankruptcy trustee rather than the plaintiff, or, if not disclosed by the plaintiff on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

TWENTY-THIRD DEFENSE

Plaintiffs' claims for breach of warranty are barred by Plaintiffs' failure to give sufficient and timely notices as required by law and by Plaintiffs' inability to show any reliance on any alleged representation or warranty.

TWENTY-FOURTH DEFENSE

Plaintiffs are barred from recovery as to any or all causes of action due to their lack of privity with Ethicon.

TWENTY-FIFTH DEFENSE

Any express or implied warranties alleged to have been made by Ethicon were disclaimed.

TWENTY-SIXTH DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

TWENTY-SEVENTH DEFENSE

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

TWENTY-EIGHTH DEFENSE

The sale, labeling and marketing of products at issue in this litigation is not, and was not, likely to mislead or deceive the public.

TWENTY-NINTH DEFENSE

The product at issue was altered after it left the control, custody and possession of Ethicon, and said alteration relieves Ethicon of any and all liability.

THIRTIETH DEFENSE

Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.

THIRTY-FIRST DEFENSE

Plaintiffs' causes of action are barred because if Plaintiffs sustained any injuries, losses, or damages, which is denied, those injuries or damages resulted from pre-existing or unrelated medical, genetic, or environmental conditions, diseases, or illnesses.

THIRTY-SECOND DEFENSE

To the extent that the injuries alleged by Plaintiffs resulted from an idiosyncratic reaction, Plaintiffs' claims are barred.

THIRTY-THIRD DEFENSE

Any recovery by Plaintiffs must be reduced or offset by amounts Plaintiffs have received or will receive from others for the same injuries claimed in this lawsuit.

THIRTY-FOURTH DEFENSE

The imposition of punitive or exemplary damages would violate Ethicon's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, the excessive fines clause in the Eighth Amendment to the Constitution of the United States, the double jeopardy clause in the Fifth Amendment to the Constitution of the United States, and equivalent applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the States of California, New Jersey, Colorado or Indiana, to the extent that punitive damages awarded to any Plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or any applicable State constitution; (3) imposed where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; or (5) imposed on the basis of anything other than Ethicon's conduct within the State where each Plaintiff resides, or in any other way subjecting Ethicon to impermissible multiple punishment for the same alleged wrong.

THIRTY-FIFTH DEFENSE

To the extent that Plaintiffs claim that CAL. CIV. CODE § 3294 applies to this lawsuit, this statute is invalid on its face or as applied to Ethicon pursuant to Article I, Section 10, Article IV, Section 2, and the First, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States; and Article I, Sections 7, 9, 15 and 17, and Article IV, Section 16 of the California Constitution.

THIRTY-SIXTH DEFENSE

Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the States of California, New Jersey, Colorado and Indiana under the Due Process clause of the Fourteenth Amendment to the United States Constitution.

THIRTY-SEVENTH DEFENSE

The Complaint fails to state a cause of action upon which relief can be granted, because the federal government has preempted the field of law applicable to the product alleged to have caused Plaintiffs' injuries, including but not limited to preemption, in whole or in part, by the Federal Food Drug and Cosmetic Act and the Medical Device amendments thereto. The granting of relief prayed for in the Complaint would impede, impair, frustrate, or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, Clause 2) of the Constitution of the United States.

THIRTY-EIGHTH DEFENSE

Plaintiffs' alleged causes of action have been improperly joined together under the applicable Rules of Civil Procedure and the laws of the States of California, New Jersey, Colorado and Indiana.

THIRTY-NINTH DEFENSE

The improper joinder of Plaintiffs' alleged causes of action violate the procedural and substantive due process rights of Ethicon under the Constitutions of the United States of America and the States of California, New Jersey, Colorado and Indiana.

FORTIETH DEFENSE

Ethicon asserts the provisions of all applicable statutory caps on damages of any sort, including punitive or exemplary damages, under the laws of the States of California, Colorado, New Jersey and Indiana.

FORTY-FIRST DEFENSE

Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because Ethicon complied with all applicable statutes and with the requirements and regulations of the FDA.

FORTY-SECOND DEFENSE

Plaintiffs' claims are barred in whole or in part by Plaintiffs' failure to assert a safer design for the products at issue.

FORTY-THIRD DEFENSE

Plaintiffs' claims are barred in whole or in part because the product(s) at issue provided a benefit to users of such product and greatly outweighed any risk created by using such product, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

FORTY-FOURTH DEFENSE

Ethicon hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-Defendant in this lawsuit.

FORTY-FIFTH DEFENSE

Ethicon reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

WHEREFORE, Defendant Ethicon prays that:

(1) Plaintiffs take nothing by reason of their Complaint;

(2) the Complaint be dismissed in its entirety and that a Judgment against Plaintiffs and in favor of Ethicon be entered;

(3) Ethicon be awarded its costs and expenses; and

(4) this Court award Ethicon any other and general or specific relief as this Court may deem just and proper.

Dated: February 14, 2011

DRINKER BIDDLE & REATH LLP

By: _____
Michelle A. Childers
Nathan D. Cardozo

Attorneys for Defendants
ETHICON, INC. (on its own behalf and behalf of its Division, ETHICON WOMEN'S HEALTH & UROLOGY, and erroneously sued as GYNECARE, INC.); and JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I, Lee Ann L. Alldridge, declare that:

I am at least 18 years of age, and not a party to the above-entitled action. My business address is 50 Fremont Street, 20th Floor, San Francisco, California 94105, Telephone: (415) 591-7500.

On February 14, 2011, I caused to be served the following document(s):

ANSWER OF ETHICON, INC. TO COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

by enclosing a true copy of (each of) said document(s) in (an) envelope(s), addressed as follows:

☑ BY MAIL: I am readily familiar with the business' practice for collection and processing of correspondence for mailing with the United States Postal Service. I know that the correspondence is deposed with the United States Postal Service on the same day this declaration was executed in the ordinary course of business. I know that the envelope was sealed, and with postage thereon fully prepaid, placed for collection and mailing on this date, following ordinary business practices, in the United States mail at San Francisco, California.

☐ BY PERSONAL SERVICE: I caused such envelopes to be delivered by a messenger service by hand to the address(es) listed below:

☐ BY OVERNIGHT DELIVERY: I enclosed a true copy of said document(s) in a Federal Express envelope, addressed as follows:

☐ BY FACSIMILE: I caused such documents to be transmitted by facsimile transmission and mail as indicated above.

Thomas V. Girardi
Amy Fisch Solomon
Amanda Kent
Girardi | Keese
1126 Wilshire Blvd.
Los Angeles, CA 90017
Telephone: (213) 977-0211
Facsimile: (213) 481-1554

Attorneys for Plaintiffs
Diane McIrvin and Alice Gale Wilson

I declare under penalty of perjury under the laws of the State of California that the above is true and correct. Executed on February 14, 2011 at San Francisco, California.

Lee Ann L. Alldridge

DRINKER BIDDLE & REATH LLP
50 Fremont Street, 20th Floor
San Francisco, CA 94105

MICHELLE A. CHILDERS (SBN #197064)
NATHAN D. CARDOZO (SBN #259097)
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Telephone: (415) 591-7500
Facsimile: (415) 591-7510

Attorneys for Defendants
ETHICON, INC. (on its own behalf and behalf of its Division, ETHICON WOMEN'S HEALTH & UROLOGY, and erroneously sued as GYNECARE, INC.); and JOHNSON & JOHNSON

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DIANE McIRVIN, an individual; and ALICE GALE WILSON, an individual,

Plaintiffs,

v.

GYNECARE, INC., a California corporation; ETHICON, INC., a New Jersey corporation; JOHNSON & JOHNSON, a New Jersey corporation; and DOE MANUFACTURERS ONE through ONE HUNDRED,

Defendants.

Case No. CGC-10-506696

ANSWER OF JOHNSON & JOHNSON TO COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

GENERAL DENIAL

Defendant JOHNSON & JOHNSON, by and through its attorneys of record Drinker Biddle & Reath LLP, hereby answers the unverified Complaint for Damages and Demand for Jury Trial ("Complaint") as follows:

By virtue of the provisions of Cal. Civ. Proc. Code § 431.30, Johnson & Johnson generally denies each and every allegation in the Complaint that relates to or is directed to Johnson & Johnson or any of its alleged agents, servants or employees. Johnson & Johnson further denies that Plaintiffs have been damaged to any extent or amount or are entitled to any

relief whatsoever from Johnson & Johnson.

Johnson & Johnson additionally denies that there is any law, fact, theory or contractual or legal relationship under which Plaintiffs are entitled to damages in any amount by this answering Defendant.

DEFENSES

FIRST DEFENSE

The Plaintiffs' claims against Johnson & Johnson are barred because Johnson & Johnson does not design, develop, manufacture, market, promote or sell any product

SECOND DEFENSE

The Complaint fails to allege facts relating to Plaintiffs' fraud claim and Plaintiffs' claims under the consumer protection acts of Colorado and Plaintiffs' states of residence with the particularity required by applicable law and is therefore insufficient to state a cause of action for fraud upon which relief can be granted.

THIRD DEFENSE

Some or all of Plaintiffs' claims may be barred by the applicable statutes of limitations and/or statutes of repose in the States of California, Colorado or Indiana.

FOURTH DEFENSE

Plaintiffs may be barred from bringing some of the claims alleged in the Complaint because Plaintiffs may lack standing and/or capacity to bring such claims.

FIFTH DEFENSE

Plaintiffs may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

SIXTH DEFENSE

The United States District Court for the Northern District of California (San Francisco Division) has jurisdiction of this case under 28 U.S.C. §§ 1332 and 1441. Diversity of citizenship exists between Plaintiff and Defendants, and it is facially evident from the Complaint that the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

SEVENTH DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the product at issue in this case and thus the "last clear chance" and assumption of the risk doctrines bar in whole or in part the damages Plaintiffs seek to recover herein.

EIGHTH DEFENSE

At all times mentioned herein, Plaintiffs were negligent, careless and at fault and conducted themselves so as to contribute substantially to their alleged injuries, losses, and damages. Said negligence, carelessness and fault of Plaintiffs bars in whole or in part the damages which Plaintiffs seek to recover herein.

NINTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were caused by the acts or omissions of third parties for which Johnson & Johnson has no legal responsibility.

TENTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use which was made of said product.

ELEVENTH DEFENSE

Johnson & Johnson states that the sole proximate cause of the injuries and/or damages alleged by Plaintiffs was the actions, omissions, or negligence of a person or persons, other than Johnson & Johnson, for whose actions, omissions, or negligence Johnson & Johnson is in no way liable. Plaintiffs are not, therefore, entitled to recover from Johnson & Johnson in this action. As to Plaintiffs or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of Plaintiffs, if any, Johnson & Johnson expressly pleads the doctrines of contributory negligence and/or comparative fault and the provisions of any applicable comparative fault or contributory negligence statute, law or policy of the States of California, New Jersey, Colorado or Indiana.

TWELFTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were not legally caused by the product at issue, but instead were legally caused by intervening and superseding causes or circumstances.

THIRTEENTH DEFENSE

Plaintiffs' claims and the defenses thereto are governed by the laws of a foreign jurisdiction.

FOURTEENTH DEFENSE

At all relevant times, Johnson & Johnson was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360c et seq., to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and other federal statutes and regulations, and Plaintiffs' claims are accordingly barred.

FIFTEENTH DEFENSE

The products at issue were accompanied by an adequate warning.

SIXTEENTH DEFENSE

Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the United States Food and Drug Administration ("FDA") is charged under law with determining the content of warnings and labeling for medical devices.

SEVENTEENTH DEFENSE

Plaintiffs cannot state a claim with regard to warnings and labeling for medical devices because the remedy sought by Plaintiffs is subject to the exclusive regulation of the FDA.

EIGHTEENTH DEFENSE

Plaintiffs' alleged damages, if any, are barred in whole or in part by Plaintiffs' failure to mitigate such damages.

NINETEENTH DEFENSE

Plaintiffs' claims for pain and suffering are barred because they violate Johnson & Johnson's rights to procedural and substantive due process and equal protection as guaranteed by

the Constitutions of the United States and the States of California, New Jersey, Colorado and Indiana.

TWENTIETH DEFENSE

The liability of Johnson & Johnson, if any, for Plaintiffs' non-economic loss must be apportioned in accordance with the provisions of CAL. CIV. CODE § 1431.2 or any similar law of the States of New Jersey or Indiana.

TWENTY-FIRST DEFENSE

The injuries resulting from the use of the product(s) referred to in the Complaint, if any, were not foreseeable to Johnson & Johnson given the state of scientific knowledge and state-of-the-art at the time of the alleged injuries. At all times relevant, the product(s) conformed to state-of-the-art specifications and state-of-scientific knowledge for such product at that time, as well as all applicable statutes and regulations, including those of the FDA.

TWENTY-SECOND DEFENSE

In the event Johnson & Johnson is held liable to Plaintiffs, which liability is expressly denied, and any other co-Defendants are also held liable, Johnson & Johnson is entitled to a percentage contribution of the total liability from said co-Defendants in accordance with principles of equitable indemnity and comparative contribution and pursuant to any applicable contribution or apportionment statute, law or policy of the States of California, New Jersey, Colorado or Indiana.

TWENTY-THIRD DEFENSE

Plaintiffs' claims against Johnson & Johnson are barred by the doctrines of equitable estoppel, laches, consent, waiver, res judicata, and collateral estoppel. Additionally, if either Plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Complaint or files for bankruptcy at some point in the future, the claims of any such Plaintiff may be "property of the bankruptcy estate" which should be prosecuted by the bankruptcy trustee rather than the plaintiff, or, if not disclosed by the plaintiff on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

TWENTY-FOURTH DEFENSE

Plaintiffs' claims for breach of warranty are barred by Plaintiffs' failure to give sufficient and timely notices as required by law and by Plaintiffs' inability to show any reliance on any alleged representation or warranty.

TWENTY-FIFTH DEFENSE

Plaintiffs are barred from recovery as to any or all causes of action due to their lack of privity with Johnson & Johnson.

TWENTY-SIXTH DEFENSE

Any express or implied warranties alleged to have been made by Johnson & Johnson were disclaimed.

TWENTY-SEVENTH DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

TWENTY-EIGHTH DEFENSE

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

TWENTY-NINTH DEFENSE

The sale, labeling and marketing of products at issue in this litigation is not, and was not, likely to mislead or deceive the public.

THIRTIETH DEFENSE

Johnson & Johnson has never had possession and control over the products at issue in this action, and therefore the Complaint as to each cause of action fails to state a claim against Johnson & Johnson.

THIRTY-FIRST DEFENSE

Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.

THIRTY-SECOND DEFENSE

Plaintiffs' causes of action are barred because if Plaintiffs sustained any injuries, losses, or

damages, which is denied, those injuries or damages resulted from pre-existing or unrelated medical, genetic, or environmental conditions, diseases, or illnesses.

THIRTY-THIRD DEFENSE

To the extent that the injuries alleged by Plaintiffs resulted from an idiosyncratic reaction, Plaintiffs' claims are barred.

THIRTY-FOURTH DEFENSE

Any recovery by Plaintiffs must be reduced or offset by amounts Plaintiffs have received or will receive from others for the same injuries claimed in this lawsuit.

THIRTY-FIFTH DEFENSE

The imposition of punitive or exemplary damages would violate Johnson & Johnson's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, the excessive fines clause in the Eighth Amendment to the Constitution of the United States, the double jeopardy clause in the Fifth Amendment to the Constitution of the United States, and equivalent applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the States of California, New Jersey, Colorado or Indiana, to the extent that punitive damages awarded to any Plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or any applicable State constitution; (3) imposed

where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; or (5) imposed on the basis of anything other than Johnson & Johnson's conduct within the State where each Plaintiff resides, or in any other way subjecting Johnson & Johnson to impermissible multiple punishment for the same alleged wrong.

THIRTY-SIXTH DEFENSE

To the extent that Plaintiffs claim that CAL. CIV. CODE § 3294 applies to this lawsuit, this statute is invalid on its face or as applied to Johnson & Johnson pursuant to Article I, Section 10, Article IV, Section 2, and the First, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States; and Article I, Sections 7, 9, 15 and 17, and Article IV, Section 16 of the California Constitution.

THIRTY-SEVENTH DEFENSE

Johnson & Johnson specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the States of California, New Jersey, California and Indiana under the Due Process clause of the Fourteenth Amendment to the United States Constitution.

THIRTY-EIGHTH DEFENSE

The Complaint fails to state a cause of action upon which relief can be granted, because the federal government has preempted the field of law applicable to the product alleged to have caused Plaintiffs' injuries, including but not limited to preemption, in whole or in part, by the Federal Food Drug and Cosmetic Act and the Medical Device amendments thereto. The granting of relief prayed for in the Complaint would impede, impair, frustrate, or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, Clause 2) of the Constitution of the United States.

THIRTY-NINTH DEFENSE

Plaintiffs' alleged causes of action have been improperly joined together under the applicable Rules of Civil Procedure and the laws of the States of California, New Jersey, and Indiana.

FORTIETH DEFENSE

The improper joinder of Plaintiffs' alleged causes of action violate the procedural and substantive due process rights of Johnson & Johnson under the Constitutions of the United States of America and the States of California, New Jersey, and Indiana.

FORTY-FIRST DEFENSE

Johnson & Johnson asserts the provisions of all applicable statutory caps on damages of any sort, including punitive or exemplary damages, under the laws of the States of California, Colorado, New Jersey, and Indiana.

FORTY-SECOND DEFENSE

Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because Johnson & Johnson complied with all applicable statutes and with the requirements and regulations of the FDA.

FORTY-THIRD DEFENSE

Plaintiffs' claims are barred in whole or in part by Plaintiffs' failure to assert a safer design for the products at issue.

FORTY-FOURTH DEFENSE

Plaintiffs' claims are barred in whole or in part because the product(s) at issue provided a benefit to users of such product and greatly outweighed any risk created by using such product, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

FORTY-FIFTH DEFENSE

Johnson & Johnson hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-Defendant in this lawsuit.

FORTY-SIXTH DEFENSE

Johnson & Johnson reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

WHEREFORE, Defendant Johnson & Johnson prays that:

(1) Plaintiffs take nothing by reason of their Complaint;

(2) the Complaint be dismissed in its entirety and that a Judgment against Plaintiffs and in favor of Johnson & Johnson be entered;

(3) Johnson & Johnson be awarded its costs and expenses; and

(4) this Court award Johnson & Johnson any other and general or specific relief as this Court may deem just and proper.

Dated: February 14, 2011

DRINKER BIDDLE & REATH LLP

By: _____
Michelle A. Childers
Nathan D. Cardozo

Attorneys for Defendants
ETHICON, INC. (on its own behalf and behalf of its Division, ETHICON WOMEN'S HEALTH & UROLOGY, and erroneously sued as GYNECARE, INC.); and JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I, Lee Ann L. Alldridge, declare that:

I am at least 18 years of age, and not a party to the above-entitled action. My business address is 50 Fremont Street, 20th Floor, San Francisco, California 94105, Telephone: (415) 591-7500.

On February 14, 2011, I caused to be served the following document(s):

ANSWER OF JOHNSON & JOHNSON TO COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

by enclosing a true copy of (each of) said document(s) in (an) envelope(s), addressed as follows:

☑ BY MAIL: I am readily familiar with the business' practice for collection and processing of correspondence for mailing with the United States Postal Service. I know that the correspondence is deposed with the United States Postal Service on the same day this declaration was executed in the ordinary course of business. I know that the envelope was sealed, and with postage thereon fully prepaid, placed for collection and mailing on this date, following ordinary business practices, in the United States mail at San Francisco, California.

☐ BY PERSONAL SERVICE: I caused such envelopes to be delivered by a messenger service by hand to the address(es) listed below:

☐ BY OVERNIGHT DELIVERY: I enclosed a true copy of said document(s) in a Federal Express envelope, addressed as follows:

☐ BY FACSIMILE: I caused such documents to be transmitted by facsimile transmission and mail as indicated above.

Thomas V. Girardi
Amy Fisch Solomon
Amanda Kent
Girardi | Keese
1126 Wilshire Blvd.
Los Angeles, CA 90017
Telephone: (213) 977-0211
Facsimile: (213) 481-1554

Attorneys for Plaintiffs
Diane McIrvin and Alice Gale Wilson

I declare under penalty of perjury under the laws of the State of California that the above is true and correct. Executed on February 14, 2011 at San Francisco, California.

Lee Ann L. Alldridge

EXHIBIT C

31 Trials Digest 3d 113 (Cal.Superior), 1999 WL 33100260
For Dockets See BC161172

Superior Court, Los Angeles County, California.

Casadei vs. Norris

TOPIC:
Synopsis: Negligence alleged in treatment of perineum tear and performance of reconstruction surgery
Case Type: Medical Malpractice; Surgeon; Medical Malpractice; Obstetrician/Gynecologist; Surgery/Procedures; Miscellaneous

DOCKET NUMBER: BC161172

STATE: California
COUNTY: Los Angeles

Verdict/Judgment Date: August 2, 1999

JUDGE: Irving S. Feffer

ATTORNEYS:
Plaintiff: John F. Denove, Cheong, Denove, Rowell, Antablin & Bennett, Los Angeles.
Defendant: Marshall Silberberg, Baker, Silberberg & Keener, Irvine.; Arthur Tuverson, Tuverson & Hillyard, Los Angeles.

SUMMARY:
Verdict/Judgment: Plaintiff
Verdict/Judgment Amount: $530,415

Range: $500,000-$999,999

Gross award of $480,415 ($52,500 past economic, $100,000 past non-economic, $87,500 future economic and $250,000 future non-economic) awarded to plaintiff Andrea Casadei plus CCP 998 costs of $44,491 plus interest at 10 percent per annum from February 13, 1998 and $50,000 non-economic damages awarded to plaintiff Bart Zeigler. Liability was allocated 100 percent to defendant Marvin Corman.
Trial Type: Jury
Trial Length: 17 days.
Deliberations: 2 days.
Jury Poll: Not reported.

EXPERTS:
Plaintiff: James Heaps, obstetrician/gynecologist, West Los Angeles.; Trudy Moss, psychologist, West Los Angeles.; Joseph Oliver, obstetrician/gynecologist, Pasadena.; Joyce B. Pickersgill Ph.D., economist, Formuzis, Pickersgill & Hunt, Santa Ana, (714) 542-8853.; Douglas Smiley, colorectal surgeon, Los Angeles.

Defendant: William A. Frumovitz, obstetrician/gynecologist, Santa Monica, (310) 829-7878.; Barbara C. Luna Ph.D., economist, White, Zuckerman, Warsavsky & Luna, Sherman Oaks, (818) 981-4226.; David Rothenberger, colorectal surgeon, Minnesota.; Thomas Sokol, colorectal surgeon, Beverly Hills.; Paul Weber, obstetrician/gynecologist, Long Beach.

TEXT:
CASE INFORMATION
FACTS/CONTENTIONS

According to Plaintiff: Plaintiffs claimed negligence in the care and treatment of plaintiff wife following the birth of their child. The plaintiffs were Andrea Casadei, 31, and Bart Ziegler, 28. The defendants were Marvin Corman, Marvin Corman, M.D. Inc., Karl Norris and Karl Norris, M.D. Inc.
Plaintiff Andrea Casadei was a patient of defendant Karl Norris, an obstetrician/gynecologist, for the pregnancy and birth of her first child. During the birth of her child on August 5, 1995 Casadei sustained a 4th degree perineum tear that was subsequently repaired by Norris. Casadei claimed that she sustained the injury because of Norris' negligence both in the repair of the tear and in the after-care.
Subsequent to Norris' care and treatment, Casadei was a patient of defendant Marvin Corman. On February 23, 1996 Casadei underwent an anovaginal reconstruction surgery that was performed by Corman. Casadei alleged that she was injured due to the negligent conduct of Corman both in the failure to obtain informed consent and in the performance of the surgery and the after-care.
Defendants denied that they were negligent and contended that all the treatment they provided was appropriate and with consent. They further contested the nature and extent of the injuries claimed. Defendant Corman, a past president of the American Society of Colorectal Surgeons, performed an operation on Casadei that was named after him. Corman claimed that it was impossible for this injury to have occurred as a result of the surgery. Corman argued that most of Casadei's complaints preexisted her delivery and the rest occurred after delivery and before Casadei saw him.

CLAIMED INJURIES
According to Plaintiff: Andrea Casadei: Severe pain; dyspareunia; fecal incontinence; three revision surgeries after February 23, 1996 surgery; inability to stand up straight or sit. Bart Ziegler: Lost consortium.

CLAIMED DAMAGES
According to Plaintiff: Andrea Casadei: Medical and related expenses (past medical paid by collateral source); $125,000 past income; $834,000 future income. Bart Ziegler: Lost consortium damages.

SETTLEMENT DISCUSSIONS
According to Plaintiff: Demand: $499,000 (CCP 998) from defendant Corman; $29,999 from Norris. Offer: None.

COMMENTS
According to Plaintiff: Defense experts Rothenberger, Sokol and Weber were expert witnesses for defendant Corman. Defense expert Frumovitz was an expert witness for defendant Norris. Marshall Silberberg represented defendants Marvin Corman and Marvin Corman, M.D. Inc. Arthur Tuverson represented defendants Karl Norris and Karl Norris, M.D. Inc.
Trials Digest, A Thomson/West business

Los Angeles County Superior Court/Downtown
31 Trials Digest 3d 113 (Cal.Superior), 1999 WL 33100260
END OF DOCUMENT

EXHIBIT D

12 Trials Digest 3d 45 (Cal.Superior), 1998 WL 866008

Superior Court, Los Angeles County, California.

Penix vs. Martin

TOPIC:
Synopsis: Surgical procedure allegedly chosen without disclosing risks/complications and because it was more expensive
Case Type: Medical Malpractice; Obstetrician/Gynecologist

DOCKET NUMBER: LC038378

STATE: California
COUNTY: Los Angeles

Verdict/Judgment Date: September 2, 1998

JUDGE: Richard A. Adler

ATTORNEYS:
Plaintiff: Brian R. Magana, Magana, Cathcart & McCarthy, Los Angeles.
Defendant: Gregory M. Hulbert, Reback, Hulbert, McAndrews & Kjar, Manhattan Beach.

SUMMARY:
Verdict/Judgment: Plaintiff
Verdict/Judgment Amount: $116,661

Range: $100,000-$199,999

Gross amount awarded.
Trial Type: Jury
Trial Length: 5 days.
Deliberations: 1 day.
Jury Poll: 12-0.

EXPERTS:
Plaintiff: William A. Frumovitz, obstetrician/gynecologist, Santa Monica, (310) 829-7878.; Thomas Lebherz, obstetrician/gynecologist, UCLA, Los Angeles.
Defendant: Stephen Rabin, obstetrician/gynecologist, Los Angeles.

TEXT:
CASE INFORMATION
FACTS/CONTENTIONS

According to Defendant: Plaintiff claimed that defendant ob/gyn unilaterally decided on a certain type of surgical procedure to remove a cyst without disclosing the risks and complications and because it was more expensive that an office procedure. The plaintiff was Patricia Penix. The defendant was Malverse Martin, an obstetrician/gynecologist. Plaintiff, who was 34 at the time, presented to defendant with gynecological complaints referable to a Bartholin's cyst. Initial treatment with antibiotics was unavailing and, accordingly, the patient returned to defendant's office with the expectation that the cyst would be 'lanced' in the office with the use of a local anesthetic. Instead of lancing the cyst as expected, however, defendant advised the patient that it was located in a 'delicate' area such that she would never be able to stand the pain and that she needed to have it surgically removed in the hospital. One week later, on September 1, 1995, defendant performed a surgical excision of the cyst. The patient ended up with substantial hypertrophic scarring of the wall of the vagina and labial hypertrophy which resulted in vaginal disfigurement and necessitated cosmetic-reconstructive surgery. The surgery was subsequently attempted by defendant six weeks following the initial surgery on October 13, 1995 and was admittedly unsuccessful and resulted in further disfigurement and scarring.

Plaintiff alleged that defendant inappropriately and unilaterally decided to perform a Bartholin's cystectomy without disclosing the inherent risks and complications attendant to such a procedure because of the substantial financial benefit garnered by performing the more complicated and involved procedure, as opposed to the simple, quick (less than five minutes) and inexpensive office procedure which should have been performed. It was further asserted that the type of procedure defendant performed was one which was reserved for middle-aged women who were suspected to have a potential Bartholin carcinoma because of the fact that it was well-known that the risks of scarring, dyspareunia, bleeding and disfigurement was likely. The standard of care mandated that the least intrusive and least risky modalities of treatment be attempted first, which would carry a 99 percent success rate without the corresponding risks of scarring and disfigurement. Opting to remove the cyst surgically as a primary procedure was inappropriate, contraindicated and below the standard of care. Plaintiff further asserted that she was told essentially that she had no choice in the modality of treatment as the cyst was located in an area that would not allow its removal in an office setting and that she would be fine and need not worry about it.

Defendant contended that he explained each of the modalities of treatment to the patient; that she was desirous of having the more extensive and involved surgical excision because it carried with it the least risks of a recurrence of the cyst, although he conceded that he did not discuss with her the potential risks of scarring, permanent dyspareunia and cosmetic disfigurement because he believed they were rare to encounter and not normally recognized risks of the procedure. Defendant asserted that the surgery was an appropriate modality of treatment which the patient herself selected and that the unfortunate complications which she experienced were not the result of negligence.

CLAIMED INJURIES

According to Defendant: Hypertrophic scarring of vaginal wall resulting in permanent dyspareunia and vaginal disfigurement.

CLAIMED DAMAGES

According to Defendant: $6,661 medical specials.

SETTLEMENT DISCUSSIONS

According to Defendant: Demand: $85,000 (CCP 998) at commencement of litigation, increased to $175,000 at close of case. Offer: $29,999.99, which was rejected (defendant had limited his consent to California Medical Board's reportable limits).

COMMENTS

According to Defendant: The jury was asked to return a verdict in excess of $400,000.

Trials Digest, A Thomson/West business
Los Angeles County Superior Court/Van Nuys

12 Trials Digest 3d 45 (Cal.Superior), 1998 WL 866008

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